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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
FONDA, KATHLEEN KAHLER

ART UNIT	PAPER NUMBER
1623	5

DATE MAILED: 04/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,047	KIM ET AL.	
	Examiner	Art Unit	
	Kathleen Kahler Fonda, Ph.D.	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2-22-02 (IDS and prel amdt) .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The phrase "comprising an active ingredient of quercetin derivatives" in claim 1, lines 1-2, renders the claim unclear as to how many derivatives must be in the claimed therapeutic agent.

Claim 2 is indefinite because the phrase "whose R_2, R_3, R_4 and R_5 are -OH as followings" in lines 3-4 does not clearly state which derivatives are intended to be within the scope of the claim.

Claim 3 is indefinite because the phrase "whose R_1 is -OH and three functional groups out of R_2, R_3, R_4 and R_5 are -OH as followings" in lines 3-4 does not clearly state which derivatives are intended to be within the scope of the claim.

Claim 4 is indefinite because the phrase "whose three functional groups out of R_1, R_2, R_3, R_4 and R_5 are -OH as

followings" in lines 3-4 does not clearly state which derivatives are intended to be within the scope of the claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by SAWRUK (A). Example I of SAWRUK teaches a tablet comprising isoquercitrin and calcium which is administered to a 61 year old woman to combat osteoporosis. Thus the claims are anticipated.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by JORDAN (B). In Examples 9 and 18, JORDAN teaches administration of compositions comprising extracts of *Larrea divaricata* and *Larrea tridentata*, respectively. At column 2, lines 41-58, JORDAN teaches that such extracts comprise numerous

quercetin derivatives, including quercetin, quercetin 7,3'-dimethyl ether (also known as rhamnazin), isoquercitrin, isorhamnetin, and rutin as recited in the claims. Thus the claims are anticipated. Applicant is advised that "for osteoporosis" is a mere statement of intended use which is not accorded patentable weight.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by HORCAJADA-MOLTENI *et al.* (W). HORCAJADA-MOLTENI teaches rat food formulated to contain rutin, and that administration of the food prevents bone loss in ovariectomized rats. Thus the claims are anticipated.

Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by ITO (V). Because ITO is in Japanese, the Examiner relies in part on Derwent abstract 1995-151458 as an indication of its contents. ITO teaches a drink comprising quercetin glycoside, cyclodextrin, and Vitamin C. See the Derwent abstract. Thus the claims are anticipated. Applicant is advised that "for osteoporosis" is a mere statement of intended use which is not accorded patentable weight.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by HSU *et al*. (F). Claim 4 of HSU teaches a pharmaceutical suppository composite comprising quercetin, isoquercetin, isorhamnetin, and rutin. Thus the claims are anticipated. Applicant is advised that "for osteoporosis" is a mere statement of intended use which is not accorded patentable weight.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by SULLIVAN *et al*. (V). At page 7 lines 4-7 of the specification, Applicant admits that SULLIVAN teaches oral and intraperitoneal administration of "the quercetin derivatives of the invention" to rats. The formulations of SULLIVAN are therapeutic agents within the scope of claims 1-5. Thus the claims are anticipated. Applicant is advised that "for osteoporosis" is a mere statement of intended use which is not accorded patentable weight.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

> subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over SAWRUK (A).

Applicant claims a therapeutic agent comprising a quercetin derivative and a pharmaceutically acceptable carrier, wherein particular carriers are recited, or wherein the agent is in a particular physical form for administration.

SAWRUK teaches as set forth above. Although SAWRUK does not exemplify any formulation other than that of Example I,

SAWRUK does state that any of various conventional excipients or physical forms for administration may be employed. See column 4, lines 14-27, which states:

> The preferred method of administration is orally in the form of tablets, capsules and the like. The oral dosage form can be prepared by conventional procedures for making pharmaceutical tablets and capsules, for example, tableting by compression or molding, encapsulation by spray drying, microencapsulation, and the like. The oral dosage form can employ conventional excipients which are pharmaceutically acceptable and pharmacologically inactive, for example, diluents, binders, lubricants, disintegrators, coloring and flavoring agents in addition to the active compounds defined herein. Examples of such excipients are vegetal silica binder, corn starch, gelatin, gums such as carboxymethyl cellulose, acacia and locust bean gum, sugars such as sucrose, dextrose and lactose, salts such as sodium chloride, and the like materials.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to formulate quercetin derivatives as claimed with any conventional carrier or in any conventional physical form for administration. A worker of ordinary skill in the art would have been motivated to do so because SAWRUK had taught that any conventional carrier or physical form for administration could be employed. The Examiner notes that all of the carriers and physical forms recited in the pending claims are art-recognized. Therefore, based on the teaching of SAWRUK, one skilled in the art would have been taught that any carrier or physical form would be

suitable for quercetin derivatives. Applicant has failed to demonstrate any unexpected result associated with a particular carrier or physical form for administration.

Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over ROMEO *et al.* (N).

Applicant claims a therapeutic agent comprising a quercetin derivative which may be quercetin-3,4',7-trimethyl ether or quercetin-3,3',4',7-tetramethyl ether, and a pharmaceutically acceptable carrier.

ROMEO teaches 3,7,4'-trimethylquercetin and 3,7,3',4'-tetramethylquercetin; see Example 3 and reference claims 4 and 5. ROMEO also states that they may be formulated as pharmaceutical preparations for tumor therapy. ROMEO does not explicitly disclose a composition comprising 3,7,4'-trimethylquercetin or 3,7,3',4'-tetramethylquercetin and a pharmaceutically acceptable carrier.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to formulate trimethylquercetin or 3,7,3',4'-tetramethylquercetin together with a pharmaceutically acceptable carrier. A worker of ordinary skill in the art would have been motivated to do so because ROMEO had taught the use of these compounds in

pharmaceutical preparations. Furthermore, reference claim 6 clearly contemplates an additional non-active agent in the composition by its reference to the quercetin compound as an "active substance" of the pharmaceutical preparation. The Examiner takes Official notice of the fact that therapeutic agents are commonly administered together with a carrier. Applicant is advised that "for osteoporosis" is a mere statement of intended use which is not accorded patentable weight.

The following references are cited to indicate the state of the art at the time of the invention more completely: Courbat (C), Cazaux *et al.* (D), Vester (E), Hollman *et al.* (U)

No claim is allowed.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see http://www.uspto.gov/ebc/index.html for more information. Also, http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

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Primary Examiner
Art Unit 1623